5

10

15

20

25

Claims:

- 1. A synergistic pharmaceutical combination suitable for the prevention or treatment of a prediabetic state, metabolic X-syndrome or diabetes mellitus as well as disorders which are associated with the states listed above, namely endogenic metabolic disorders, insulin resistance, dislipidemia, alopecia, diffuse effluvium, polycystic ovary syndrome and/or other diabetic complications comprising
- (a) a first pharmaceutical composition containing cicletanine or a pharmaceutically suitable acid addition salt thereof and one or more conventional carrier(s), and
- (b) a second pharmaceutical composition containing an antidiabetic or anti-hyperlipidemic active agent or, if desired and chemically possible, a pharmaceutically suitable acid addition salt or a salt formed with a pharmaceutically suitable base thereof and one or more conventional carrier(s).
- 2. A pharmaceutical combination of Claim 1 in which a single pharmaceutical composition comprises both the cicletanine or a pharmaceutically suitable acid addition salt thereof and the antidiabetic or anti-hyperlipidemic active agent or, if desired and chemically possible, a pharmaceutically suitable acid addition salt or a salt formed with a pharmaceutically suitable base thereof.
- 3. A pharmaceutical combination of Claim 1 or 2 comprising a thiazolidinedione derivative or a pharmaceutically suitable acid addition salt thereof as the antidiabetic active agent.
 - 4. A pharmaceutical combination of Claim 1 or 2 comprising

a sulfonylurea or a pharmaceutically suitable acid addition salt thereof as the antidiabetic active agent.

5. A pharmaceutical combination of Claim 1 or 2 comprising a biguanidine derivative of the formula I, wherein

5

10

15

20

wherein

R¹, R², R³ and R⁴ represent, independently, a hydrogen atom, a C₁₋₁₀ alkyl group, a naphthyl group, a phenyl group or a phenyl(C₁₋₄ alkyl) group, wherein in both former cases the phenyl group is optionally substituted by 1-3 substituents which can be, independently, a halo atom, a C₁₋₄ alkyl group or a C₁₋₄ alkoxy group,

with the proviso that one of R¹, R², R³ and R⁴ is other than a hydrogen atom, or

R¹ and R² together with the adjacent nitrogen atom and/or R³ and R⁴ together with the adjacent nitrogen atom form a 5- or 6-membered, saturated, unsaturated or aromatic ring that can be fused with a further 5- or 6-membered saturated,

5

10

15

20

25

unsaturated or aromatic ring optionally containing also a nitrogen atom.

or a pharmaceutically suitable acid addition salt thereof as the antidiabetic active agent.

- 6. A pharmaceutical combitation of Claim 5 comprising metformin or a pharmaceutically suitable acid addition salt thereof as the antidiabetic active agent.
- 7. A pharmaceutical combination of Claim 1 or 2 comprising insulin, pioglitazone, troglitazone, ciglitazone, rosiglitazone, mitiglinide, repaglinide, senaglinide, tolbutamide, chlorpropamide, tolazamide, acetohexamide, glyburide, glipizide, gliclazide, glimepiride, gliquidone, glibornuride, glisoxepid, glibenclamide, glisentide, glisolamide, glybuzole, glyclopyramide, metformin, buformin, phenformin, miglitol, acarbose or voglibose, clofibrate, gemfibrozil, simfibrate, etofibrate, ciprofibrate, ronifibrate, lovastatin, fluvastatin, pravastatin, simvastatin, atorvastatin, acipimox, niceritrol, nicomol, nicoclonate, colestipol, cholestyramine, polidexide or, if desired and chemically possible, a pharmaceutically suitable acid addition salt or a salt formed with a pharmaceutically suitable base thereof as the antidiabetic or anti-hyperlipidemic active agent.
 - 8. Use of cicletanine or a pharmaceutically suitable acid addition salt thereof for the preparation of a pharmaceutical composition having insulin sensitizing effect.
 - 9. The use of Claim 5 in which each pharmaceutical composition contains 30 to 100 mg of cicletanine or cicletanine

WO 2004/091612 PCT/HU2004/000037

hydrochloride.

10. A method for the treatment or the prevention of a prediabetic state, metabolic X-syndrome or diabetes mellitus as well as disorders which are associated with the states listed above, namely endogenic metabolic disorders, insulin resistance, dislipidemia, alopecia, diffuse effluvium, polycystic ovary syndrome and/or other diabetic complications, in which the patient suffering from or threatened by said states is treated with a therapeutically effective amount of cicletanine or a pharmaceutically suitable acid addition salt thereof.